DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 5, 2015

Terumo Cardiovascular Systems Corporation
Garry A. Courtney, MBA, RAC
Senior Manager, Regulatory Affairs
125 Blue Ball Road
Elkton, MD 21921

Re: K150536
Trade/Device Name: Terumo Circuit Tubing
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, or Tubing
Regulatory Class: Class II
Product Code: DWF
Dated: April 2, 2015
Received: April 7, 2015

Dear Mr. Courtney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

TERUMO

SECTION 4
Indications for Use

510(k) Number (if known): K150536

Device Name: Terumo® Circuit Tubing

Indications for Use:

The Terumo® Circuit Tubing is intended to provide a conduit for extracorporeal fluid flow during cardiopulmonary bypass procedures when interconnecting components of the bypass circuit.

The tubing is intended to be used in procedures lasting not more than 6 hours.

Prescription Use **XX** OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

TERUMO

Primary Contact:
This submission was prepared in March 2015 by**:**

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This submission was prepared for:

Terumo Cardiovascular Systems Corporation
28 Howe Street
Ashland, MA 01721

Device Names/Classifications:

Proprietary Name	Classification Name	Common Name
Terumo® Circuit Tubing	Cardiopulmonary Bypass Catheter, Cannula or Tubing	Circuit Tubing

Predicate Device(s):
The device submitted in this 510(k) maintains characteristics that are substantially equivalent to the following devices:

- Terumo® Circuit Tubing, Part Number 0017-11031A. This tubing has preamendment status as the product was included in Convenience Kits manufactured by Terumo Cardiovascular since prior to May 28, 1976.

Indications for Use*:*
The Terumo® Circuit Tubing is intended to provide a conduit for extracorporeal fluid flow during cardiopulmonary bypass procedures when interconnecting components of the bypass circuit.

The tubing is intended to be used in procedures lasting not more than 6 hours.

Conditions of Use:
The Terumo® Circuit Tubing can be used in any cardiopulmonary bypass procedure where an extracorporeal circuit is required and where the conduit tubing necessary is 3/32" ID x 1/32" wall thickness.

Principles of Operation and Technology*:*
The Terumo® Circuit Tubing that is the subject of this application uses the same technology as the predicate Terumo® Circuit Tubing that is the subject of K023056. Both are tubing segments that provide a conduit for the flow of extracorporeal fluids within the bypass circuit. Each of the tubing segments is typically used as a conduit between other devices within the circuit. Each tubing allows for the flow of fluids created by either gravity, vacuum and pumping.

Design and Materials:
The blood-contacting material that is used in the construction of the Terumo® Circuit Tubing is flexible polyvinyl chloride (PVC) resin.

The design differences between the subject Terumo® Circuit Tubing and predicate Terumo® Circuit Tubing device is the tubing dimensions and the durometer (tubing hardness). The differences are presented below:

Device Characteristics	Subject: 0017-40152	Predicate: 0017-11031A
Materials of Construction	Flexible PVC resin	Flexible PVC resin, PMEA Coating
Shore A Durometer Hardness Measurement	68	70
Tubing Dimensions (I.D. x wall thickness)	3/32" x 1/32"	3/32" x 1/16"

Performance Evaluations:
Terumo Cardiovascular Systems conducted the following *in-vitro* performance evaluations to demonstrate the functional equivalence of the subject Terumo® Circuit Tubing to the predicate Terumo® Circuit Tubing.

- Tubing Connection Strength
- Leakage Testing
- Dimensional Analysis
- Visual for abnormalities

Substantial Equivalence Comparison:
In demonstrating substantial equivalence of the Terumo® Circuit Tubing to the predicate Terumo® Circuit Tubing a comparative study and/or assessment was performed in each of the following areas:

- Indications for Use
- Duration of use
- Target population
- Product labeling
- Product design
- Materials used in device construction
- Principles of Operation and Technology
- Device Performance

Substantial Equivalence Statement:
The new Terumo® Circuit Tubing is substantially equivalent in product indications, target population, duration of use, labeling, design, materials, principles of operation and technology, and performance to the predicate Terumo® Circuit Tubing (Preamendment).

Additional Safety Information:

- Sterilization conditions for the Terumo® Circuit Tubing will be validated in accordance with applicable standards and guidelines to provide a Sterility Assurance Level (SAL) of 10^{-6}. Terumo Cardiovascular Systems further asserts that the ethylene oxide residues will not exceed stated or implied maximum residue limits at the time of product distribution.

Conclusion:

Based upon the comparative studies and analyses, Terumo Cardiovascular Systems concludes that the Terumo® Circuit Tubing is *substantially equivalent* to the predicate Terumo® Circuit Tubing. It is further concluded that any recognized differences noted during the assessments do not raise new issues of patient/user safety or product effectiveness.